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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,943	01/29/2002	Henry Wolfe	WOLF3002/REF/C	4872

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/01/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,943

Applicant(s)

WOLFE ET AL.

Examiner

Michael G. Hartley

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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***Response to Amendment***

The preliminary amendment filed 1/29/2002 has been entered..

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 14, 23, 25, 27, 28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5 and 27, the recitation of and “derivatives thereof” is indefinite because the scope of this recitation cannot be ascertained. It is not clear what chemical moieties would be considered derivatives thereof. It is suggested that “and derivatives thereof” is canceled from claim 5 to obviate this rejection.

In claim 5, the use of the parenthesis-enclosed text is confusing and should be deleted because it is not clear what these parenthesis are being used to denote and/or why they are present.

In claim 14, the recitation of “carboxyl derivative” is indefinite because it is not clear what compounds are encompassed thereby. As stated above, it is not clear what all would be considered a derivative thereof (e.g., of a carboxyl). It is suggested that “or carboxyl derivative” is canceled from the claim.

In claim 23, the recitation of “an analogue thereof” is indefinite because it is not clear what is encompassed thereby. It is unclear what an analogue thereof would constitute and what and would not be encompassed thereby. It is suggested that this recitation be deleted from the claim.

Claim 25 is indefinite because it is unclear what is being claimed, for example, it is unclear what is meant by “said core moiety is as defined” or how this claim is further limiting its base claim. There appears to be no limitation in this claim. It is unclear to what “as defined” means because it is unclear what is doing the defining. The recitation of “dendrimeric polymer” in the preamble does not limit the

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claim. A preamble is generally not accorded any patentable weight where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In claim 27, the method that is being claimed cannot be determined because it is unclear what the starting material encompasses as well as is meant by "deprotecting" or "protected derivative." It is unclear what is meant by this or what step or steps are being performed. If the derivative is not known it cannot be clear how it is protected to start with or deprotected in a step. Also, what and how it is protected. It is unclear if it is physically protected (i.e., placed in a container, refrigerated, etc.) or if some chemical group is somehow protected with a leaving group. The method being claimed herein cannot be determined, since neither the starting material(s) nor the step(s) involved are clear.

In claim 28, the recitation of "deprotecting any protected group" is unclear, since it is unclear what the protected groups encompass or how they are deprotected. It is unclear if this step is necessary, since it states "deprotecting any protected groups" which appears to mean they may or may not be present. It is unclear when this step would be necessary or what it constitutes.

Claim 30 provides for the use of a compound but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

#### ***Claim Rejections - 35 USC § 101***

Claim 30 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tomalia (US 5,714,166).

Tomalia discloses a compound comprising a radially asymmetric dendrimeric polymer (e.g., a dendrimer) which comprises a plurality of amine-containing acids, specifically the amino acid, lysine. See the compound and method of making thereof set forth in example 75. Also, see claims 65 and 66. The dendrimers are linked with at least one reporter, such as, paramagnetic metals, radionuclides, etc. for use in method of imaging, see column 18, lines 45+.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Tomalia (US 5,714,166).

Tomalia discloses a compound comprising a radially asymmetric dendrimeric polymer (e.g., a dendrimer), linked to at least one reporter, which comprises a plurality of amino acids, as discussed above. Tomalia teaches that various reporters and/or amino acids may be used interchangeably, as equivalents, in the compounds to yield useful imaging agents for a variety of imaging modalities, see column 18 and claims 65 and 66.

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While Tomalia fails to specifically disclose compounds, methods of making and using thereof comprising all of the same reporters, and amino acids, etc. encompassed by the claims, it would have been obvious to one of ordinary to use various reporters, amino acids, etc. in the compounds and methods disclosed by Tomalia because Tomalia teaches that various reporters (e.g., chelated metals, etc.), various amino acids (e.g., arginine, lysine) etc., may be employed as equivalents to yield various compounds useful for particular imaging modalities. One of ordinary skill in the art would have been motivated to substitute one reporter for another to obtain a compound useful for MRI or radioimaging, and to substitute one amino acid for another because Tomalia teaches their equivalence in the disclosed compounds and methods.

### ***Specification***

The disclosure is objected to because of the following informalities: The specification fails to include a section of "Brief Description of the Drawings" as required. Note, Figures 1A and 1B have been filed with the application. Appropriate correction is required.

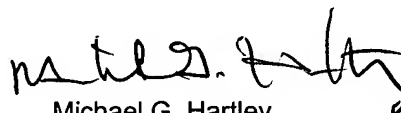
### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

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